IRB PRODUCT PERFORMANCE REVIEW

PM: 10 04-03-92

65233-R
TREO SPF15
Primavera Laboratories (distributor) D: 173192
Corwood Laboratories Inc. MRID: 421513-11
Hauppauge, NY 11788

FORMULATION

Citronella(Java).....0.05%

The following are listed as inerts:

[redacted]

Sunscreen and Insect Repellent Lotion

7.8 lbs. per gallon INERT INGREDIENT INFORMATION IS NOT INCLUDED

INTRODUCTION

Application for new registration. P.M. requests review of efficacy data. Citronella is the only active ingredient in the proposed formulation. (We recall the product as having multiple actives when originally submitted to the old PM-17, but these have apparently been deleted). Citronnella has been previously registered for topical human use at up 100%. We have no record of citronella being effective as a repellent at 0.05% [redacted]

INERT INGREDIENT INFORMATION IS NOT INCLUDED

USES

Label claims indicate insect and tick protection. Deer tick is specifically claimed. Specific insects are not listed on the label.

SUBMITTED DATA

All studies from Dr. Scott P. Carroll, Biologist, Davis, CA 95616. (916)-758-4728. All studies listed as being in compliance with GLPs.

1. MRID 421513-11. Field Test Mosquito Repellent Efficacy.

First test run at Galveston, TX. Second test run in "upper Florida keys". Both studies from 1989. "Lower" arms of subjects treated with either a commercial 35% deet product or the candidate material. Counts are both lites and bites over a 2 hour period. Mosquitoes identified only to genus, and are described as Culex and Aedes species. Results:

Material	Lites	bites
Treo spf15	7	5
Cutters Deet	7	3
untreated	211	170

Submitted study is invalid. The number of subjects is not reported, the species of mosquito is not identified, the evaluation method is not well described and the counts from two separate tests have been combined. The dosages were not reported. The study does not provide first confirmed bite protection time as is required in the Pesticide Assesment Guidelines, Subdivision G Product Performance, Section 95-9.

2. MRID 421513-12. Field Test, Mosquito Repellent Efficacy. Tests from Utah. Spp. identified as Culex tarsalis and Aedes dorsalis. One hour observation to lower arm of subjects on 4 days in July of 1989. Again, both lite and bite counts recorded. Results:

Material	Lites	Bites
Treo spf15	18	16
Deepwoods Off	7	3
untreated	500	451

Submitted study is invalid. The number of subjects is not reported, and the counts from several days of testing have been combined. Dosage was not reported. The study does not provide first confirmed bite protection time as is required in the Pesticide Assesment Guidelines, Subdivision G Product Performance, Section 95-9.

3. MRID 421513-13. Field Test. Tick Repellent Efficacy. Ixodes dammini. Study conducted on Nantucket Island, MA over 3 days in October, 1989. Study uses standard flannel flags for tick collection. Reported results:

Material	Number of Ticks Attached
Treo spf15	0
Tick Garde	0
untreated	20

Study invalid. It is not reported whether the results represent a total or an average of the 3 days. The time or area flagged was not reported. The dosage to each flag was not reported. Deer ticks don't flag very well compared to other ticks, so the low numbers aren't considered unusual. Deet is not usually 100% effective, however, and this leads us to question the infestation pressure in this study. Were all ticks positively identified as deer ticks, and how were they I.D.'d?

4. MRID 421513-14. Field Test. Simuliid blackfly Repellent Efficacy. Study done in the National Jaguar Preserve in the Republic of Belize, January 1900. Lower arms treated, exposed for one hour. Dose not reported. The species of blackfly was not identified.
Results:

Material	Total Bites
Treo spf15	0
Cutters	0
untreated	55

Study invalid. The number of subjects or dose was not reported. The species of blackfly was not identified.

5. MRID 421513-15. Laboratory Test. Tick Repellent Efficacy. Study done at the Department of Biology, University of Utah, in October, 1989. Wild deer ticks field collected from MA. 4 ticks placed in a 1-2 cm. wide and 10 cm diameter(treated)width ring in the center of a 15 cm diameter disc of filter paper. Results:

Material	No. times repelled	Total time for 4 ticks to cross twice
Treo spf15	16	19
Treo spf15	21	24
Tick Garde	1	6
untreated	0	2

We find these results confusing, especially considering the prior field results of 100% efficacy for Tick Garde as described in a field study. Again, the positive I.D. of the ticks should be confirmed.

CONCLUSIONS

1. The submitted data are inadequate to support label claims. While no specific insects are listed on the label, we assume mosquitoes and blackflies are implied as these are the insect pests represented in the submitted studies.

a. Mosquitoes. The submitted studies are not valid for the reasons cited in the study evaluations above. As we have no record of citronella being effective at the low percentage in this formulation, acceptable studies should represent the genera Anopheles, Aedes, and Culex. Other general such as Culiseta or Psorophora would also be desirable. Studies must be properly replicated such that statistical analysis can be performed. The dosage must be reported. The species must be identified. The qualifications of the participants should be included. The protection time (such as first confirmed bite) must be evaluated and determined.

b. Blackflies. Only a single study from outside the U.S. was submitted. The species was not identified and the degree of replication was not reported. Several studies utilizing species occurring in the U.S. must be submitted to support this claim. Again, the species must be identified, the dosage reported and the study properly replicated.

c. Deer Ticks. For the flag study, important details as listed above were not reported. The laboratory study shows that the product has potential, but cannot stand on its own to support the performance of the product. The deer tick is a very difficult arthropod to study, as so many of the wild ticks harbor lyme disease, and to our knowledge, a "clean" colony is as yet unavailable. For this reason it may be possible to utilize a surrogate species, such as Dermacentor variabilis, on human subjects and bridge the data using deer ticks on appropriate inanimate surfaces (such as cotton/polyester clothing). We would be happy to discuss such a testing regime with the applicant.

2. It is very difficult to interpret the submitted data as the reports lack essential information. See comments on the individual studies above. The applicant is referred to the Pesticide Assesment Guidelines, Subdivision G Product Performance Section 95-9 for details. Also recommended is the appendix item 7, on Human and Pet treatments. These publications should be available from NTIS. ASTM also has published test methods for mosquitoes. We strongly suggest that the applicant contact the USDA Insects Affecting Man and Animals Laboratory in Gainesville, FL for additional advice/assistance on conducting such studies.

3. It should be noted that the proposed product is only 0.05% citronella. This is less than one hundredth of the lowest concentration of citronella we have ever seen registered. For this reason we strongly suspect that other materials in the proposed formulation are also active ingredients. To confirm which ingredients are active, we suggest that lab studies be performed on the other consituents to ascertain whether they are inert or active in the formulation.

LABELLING

1. The labeling must state the insects for which the product is intended for use.

2. The present label indicates protection against ticks in general along with the deer tick. The applicant should be informed that a general tick claim must be supported by other species than the deer tick alone.

3. PM Note claims "DEET Free/R11 Free".

Phil Hutton
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Insecticide/Rodenticide Branch